DEPARTMENT OF HEALTH & HUMAN SERVICES

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STATEMENT OF

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INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Robert J. Meyer, M.D., Director of the Office of New Drug Evaluation II, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA or the Agency). I oversee CDER's Division of Anesthetic, Critical Care and Addiction Drug Products. This division works closely with CDER's Controlled Substances Staff, which coordinates CDER's activities related to controlled substances and the Drug Enforcement Administration (DEA). I appreciate the opportunity to talk to you today about FDA's role in preventing prescription drug abuse.

FDA is aware of and concerned about reports of prescription drug abuse, misuse, and diversion from approved medical uses. We recognize the seriousness of this issue and sympathize with the families and friends of individuals who have lost their lives as a result of prescription drug abuse and misuse. The Agency has taken many steps to prevent abuse and misuse of prescription drugs, while making sure they are available for patients who need them. FDA is committed strongly to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely manner and monitoring products for continued safety after they are in use.

BACKGROUND

Millions of Americans suffer from chronic pain. Medical and lay literature document inadequacies of the treatment of pain, both from cancer and from non-malignant causes. A consensus statement from the National Cancer Institute Workshop on Cancer Pain indicated that the "under-treatment of pain and other symptoms of cancer is a serious and neglected public health problem." A report by the Agency for Healthcare Research and Quality concluded that, "half of all patients given conventional therapy for their pain…do not get adequate relief." The Joint Commission on Accreditation of Healthcare Organizations regards the evaluation of pain in hospitalized patients as a routine requirement of proper management, akin to assessing temperature, pulse or blood pressure, stating that, "Unrelieved pain has enormous physiological and psychological effects on patients. The Joint Commission believes the effective management of pain is a crucial component of good care. …Research clearly shows that unrelieved pain can

slow recovery, create burdens for patients and their families, and increase costs to the health care system." Pain of moderate to severe intensity affects many aspects of patients' lives, including enjoyment, work, mood, activity level, and ability to sleep or even walk. While a variety of drugs is available for the treatment of moderate to severe pain, for many patients, adequate pain relief will occur only through the proper, informed use of opiates as a part of their treatment.

FDA's goals are to assure that patients who require opioids for pain control maintain appropriate access to them through informed providers, while misuse, abuse and diversion of these products is limited to the extent possible. FDA takes its responsibility in meeting these goals very seriously. Given the broad scope of factors at issue, to achieve these goals it is essential that FDA work in concert with other government agencies, professional societies, patient advocacy groups, industry, and others to share information and coordinate activities.

FDA is concerned about the increasing abuse of prescription opioid drugs. Abuse of opioid analgesics (controlled drugs that include oxycodone, morphine, fentanyl and hydrocodone), has risen steadily over the past five years. By contrast, rates of abuse of illicit drugs have been generally stable over the same time period.

The Substance Abuse and Mental Health Services Administration (SAMHSA), part of the Department of Health and Human Services (HHS), annually conducts the National Survey on Drug Use and Health on a random sample of U.S. households to determine the prevalence of non-medical use of illicit and prescription drugs. According to the 2004 National Household Survey on Drug Use and Health, people who had used pain relievers non-medically at least once during their lifetime increased 7 percent from 2002 to 2004, for a total of 31.8 million Americans.

A significant increase was reported in lifetime (i.e., people who have ever used) non-medical use of pain relievers between 2002 and 2003 among persons aged 12 or older, from 29.6 million to 31.2 million. The prevalence of lifetime non-medical use of oxycodone-containing analgesics increased from an estimated 11.8 million users in 2002 to 13.7 million users in 2003. Lifetime

non-medical use of OxyContin specifically increased from a prevalence of approximately 400,000 in 1999 to 1.9 million in 2002 and to 2.8 million in 2003.

The reported rise of prescription drug abuse is corroborated by data on the consequences of such use. SAMHSA's Drug Abuse Warning Network (DAWN) surveys a national sample of emergency departments (EDs). DAWN captures drug-related visits to EDs, contacts for non-medical use of substances for psychic effects, overdose, dependence, or suicide attempts. ED contacts increased from 69,011 in 1999 to 119,185 in 2002 for narcotic analgesics, both single and combination products. A subset of these data assessing oxycodone (both single and combination products) shows that ED visits increased from 6,429 in 1999 to 22,397 in 2002. For oxycodone sustained-release products, ED mentions increased from 1,178 in 1999 to 14,087 in 2002. The Treatment Episode Data Set (TEDS), also administered by SAMHSA, collects data on admissions to federally funded drug and alcohol addiction treatment programs. Between 1999 and 2003, treatment admissions for opiate drug addiction treatment (exclusive of heroin) increased from 1,382 admissions in 1999 to 9,171 in 2003.

THE FDA DRUG APPROVAL PROCESS

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA is responsible for ensuring that all new drugs are safe and effective. Before any drug is approved for marketing in the U.S., FDA must decide whether the studies submitted by the drug's sponsor (usually the manufacturer) have adequately demonstrated that the drug is safe and effective under the conditions of use proposed in the drug's labeling. It is important to realize, that "safe" does not mean free of risk, and that there always is some risk of potential adverse reactions when using prescription drugs. FDA's approval decisions, therefore, always involve an assessment of the benefits and the risks for a particular product. When the benefits of a drug are thought to outweigh the risks, and the labeling instructions allow for safe and effective use, FDA considers a drug safe for approval and marketing.

During the approval process, FDA assesses a drug product's potential for abuse and misuse. Abuse liability assessments are based on a composite profile of the drug's chemistry,

pharmacology, clinical manifestations, similarity to other drugs in a class, and the potential for public health risks following introduction of the drug to the general population. If a potential for abuse exists, the product's sponsor is required to provide FDA with all data pertinent to abuse of the drug, a proposal for scheduling under the Controlled Substances Act (CSA), Title 21, *United States Code* (U.S.C.) §801 et seq., and data on overdoses.

The CSA requires the Secretary of Health and Human Services to notify the Attorney General through the DEA, if a "new drug application is submitted for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, …" because it would then appear that the drug had abuse potential (21 U.S.C. §811(f)). HHS has delegated this function to FDA. The Agency assesses preclinical, clinical, and epidemiological data to determine whether a drug under review requires abuse liability studies, scheduling under the CSA, or a risk minimization action plan, (RiskMAP) designed to reduce abuse, overdose, or diversion.

FDA's job is not over after a drug is approved. The goal of FDA's post-marketing surveillance is to continue to monitor marketed drugs for safety. This is accomplished by reassessing drug risks based on new data obtained after the drug is marketed and recommending ways of trying to manage that risk most appropriately.

OXYCONTIN (oxycodone HCl)

OxyContin is a narcotic drug approved by FDA on December 12, 1995, for treatment of moderate to severe pain. The active ingredient in OxyContin is oxycodone HCl (hydrochloride), an opioid agonist with an addiction potential similar to that of morphine. Opioid agonists are substances that act by attaching to specific proteins called opioid receptors, which are found in the brain, spinal cord, and gastrointestinal tract. When these drugs attach to certain opioid receptors in the brain and spinal cord they can effectively block the transmission of pain messages to the brain. OxyContin is formulated to release oxycodone HCl in a slow and steady manner following oral ingestion. The drug substance oxycodone, however, has been marketed in the U.S. for many decades and is available in a wide variety of immediate release dosage forms, including both single entity and combination products.

At the time of approval, the abuse potential for OxyContin was considered by FDA to be no greater than for other Schedule II opioid analgesics that already were marketed in the U.S. Schedule II provides the maximum amount of control possible under the CSA for approved drug products. Based on the information available to FDA at the time of its approval, including the record of other modified release Schedule II opioids, the widespread abuse and misuse of OxyContin reported over the past few years were not predicted. In fact, at the time of its approval, FDA believed that the controlled-release characteristics of the OxyContin formulation, when taken properly, would result in less abuse potential, since the drug would be absorbed slowly and there would not be an immediate "rush" or high that would promote abuse. In part, FDA based its judgment of the abuse potential for OxyContin on the prior marketing history of a similar product, MS-Contin, a controlled-release formulation of morphine that was marketed in the U.S. by Purdue Pharma without significant reports of abuse and misuse for many years. At the time of OxyContin's approval, FDA was aware that crushing the controlled-release tablet followed by intravenous injection of the tablet's contents could result in a lethal overdose. A warning against such practice was included in the approved labeling. FDA did not anticipate, however, nor did anyone suggest at the time, that crushing the controlled-release capsule followed by intravenous injection or snorting would become widespread and lead to a high level of abuse.

FDA COLLABORATES WITH OTHER GOVERNMENT AGENCIES, PROFESSIONAL GROUPS, AND INDUSTRY

The President's 2005 National Drug Control Strategy has recognized the effectiveness of state prescription drug monitoring programs, and called on the pharmaceutical industry, medical community and state governments to become partners in an effort to prevent the illegal sale, diversion, and use of prescription drugs in a way that does not impede legitimate medical needs.

Under the FD&C Act, FDA is responsible for the approval and marketing of drugs for medical use and for monitoring products for continued safety after they are in use, including controlled substances. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. The CSA separates controlled substances into five schedules, depending

upon their abuse potential and medical use. Schedule I controlled substances have the highest potential for abuse and have no medical use while Schedule V substances have the lowest abuse potential. Schedule II substances also have a very high potential for abuse but are approved for medical use. Schedules III, IV, and V substances and drugs have lower abuse potential and fewer controls under the CSA. Some controls that are specific to Schedule II drugs under the CSA include the requirement that DEA grant manufacturing quotas and a prohibition on refills of prescriptions for these drugs.

FDA is continuing to meet with DEA, SAMHSA, the National Institute on Drug Abuse (NIDA), the Office of National Drug Control Policy (ONDCP), the Centers for Disease Control and Prevention, the American Medical Association (AMA), and industry to share information and insights needed to address the problem of prescription drug abuse as described below.

FDA and DEA meet regularly to discuss new ways to prevent prescription drug abuse and misuse. A description of joint investigative efforts is given later in the enforcement section of this testimony. In addition to assisting one another with criminal investigations, both agencies currently are working together on the following initiatives:

- *State Prescription Drug Monitoring Programs* – States that have monitoring programs have shown lower levels of abuse and misuse of scheduled drugs than states that do not have such programs. These programs facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled prescription drugs. Approximately 18 states have some kind of monitoring program in effect. While they vary in resources, methods, and data access by health care professionals, the programs share the objective of preventing and reducing inappropriate prescribing and dispensing, drug diversion, and drug abuse.
- *Task Force Participation* – Agents of FDA's Office of Criminal Investigations (OCI) frequently participate in and/or assist many DEA-led Federal-state task forces throughout the country focusing on the illegal sale of controlled prescription drugs. Both agencies are members of the following working groups: Cross Border Pharmacy Working Group, Permanent Forum on International Pharmaceutical Crime, Interagency Committee on Drug Control, Federal Trade Commission/FDA Health Fraud Working Group, and a working group composed of representatives from HHS (including FDA, SAMHSA, the National Institutes of

Health, and NIDA), DEA, ONDCP, and other agencies to address issues of drug abuse and control under the CSA. In addition, FDA is a member, along with other HHS agencies (SAMHSA and NIDA), DOJ, ONDCP, and other Federal agencies, of the Synthetic Drugs Interagency Working Group, which was established to implement the recommendations of the National Synthetic Drugs Action Plan. Prescription drug abuse is one of the topics that the Working Group's recommendations address.

- *Assessment of New Products With Abuse Potential* – FDA provides DEA with a scientific assessment of a new drug product's potential for abuse and misuse. In addition, DEA often participates in FDA public meetings to provide advice and recommendations to the Agency on scheduled drugs.

In January 2003, FDA and SAMHSA launched a joint prescription drug abuse prevention education effort, with the primary goal of preventing and reducing the abuse of prescription drugs, especially narcotic opiate pain relievers by teens and young adults. This campaign includes brochures and posters, as well as print and television educational advertising highlighting the risks of prescription opiate analgesic abuse. In particular, the campaign highlights the potentially lethal risks of abuse of sustained release opioid analgesics such as OxyContin.

FDA is working with professional societies, including the AMA, to help develop educational programs for physicians regarding sound use of potent opiate analgesics. This effort includes education about the risks of overdose, misuse, abuse, and diversion of scheduled substances as well as ways to manage these risks while ensuring proper treatment of patients with pain.

FDA/DEA ENFORCEMENT EFFORTS TO ADDRESS ILLEGAL PRESCRIPTION DRUG SALES

FDA's enforcement efforts to address the problem of diversion and illegal sales of controlled substances, particularly opiates like long-acting oxycodone, have grown in recent years. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. However, the complexity of the cases and the solutions to the problems of misuse, overdose, and diversion of prescription drugs, especially of high concentration opioid analgesic drugs, requires

the collaboration of DEA and FDA as well as state and non-governmental entities. FDA's enforcement efforts to address the problem of diversion and illegal sales of controlled substances, particularly opiates like long-acting oxycodone, have grown in recent years.

FDA's OCI works closely with DEA on criminal investigations when there is a nexus between sales of non-controlled and controlled substances over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances. For example, in August 2003, as a result of an extensive, cooperative law enforcement effort that involved DEA and FDA, as well as local and state police in Indiana, the U.S. Attorney's Office announced a 24-count indictment against four individuals who allegedly conspired to dispense prescription drugs, including controlled substances, outside the scope of a legitimate professional practice and absent legitimate medical purposes. Another case conducted by FDA, DEA, the Internal Revenue Service, and the U.S. Attorney's Office resulted in a guilty plea by a medical doctor for the role he played in prescribing prescription drugs via a web-based pharmacy without establishing a patient history or performing a mental/physical exam of patients. The cases cited are just two examples of enforcement actions that have been taken. FDA, DEA, FBI, and the Department of Justice (DOJ) have worked together to pursue other significant Internet pharmacy cases involving prescription drugs, and these enforcement efforts will continue.

Since 2001, FDA's OCI investigations relating to OxyContin have resulted in 66 arrests and 39 convictions. The remaining arrests are pending further judicial action. These are joint cases with DEA. OCI was invited to participate because of a possible nexus with non-controlled drugs under FDA authority. FDA looks forward to continuing our collaboration with DEA to address mutual concerns regarding the abuse, misuse and illegal diversion of OxyContin and other controlled substances; and our efforts to hold criminally responsible those individuals involved in such activities. This relationship will continue to be important as the Federal government addresses the increasing number of websites that offer controlled substances for sale.

On November 15, 2004, in collaboration with DEA, FDA stepped up its efforts to improve the safety and security of the nation's drug supply through the use of radiofrequency identification (RFID), a state-of-the-art technology that uses electronic tags on product packaging to allow manufacturers and distributors more precisely to track drug products as they move through the chain of custody, from the point of manufacture to the point of dispensing. It is similar to the technology used for tollbooth and fuel purchasing passes. FDA launched this effort by publishing a Compliance Policy Guide (CPG) for implementing RFID feasibility studies and pilot programs that are designed to enhance the safety and security of the drug supply. This action continues FDA's commitment to promote the use of RFID by the U.S. drug supply chain by 2007.

FDA SEEKS EXPERT ADVICE FROM NON-AGENCY EXPERTS ON MEDICAL USE OF OPIOID ANALGESICS

FDA routinely convenes panels of non-Agency experts to seek outside advice. Outside experts add a wide spectrum of judgment, outlook, and state-of-the-art experience to drug issues confronting FDA. These expert advisers add to FDA’s understanding, so that final Agency decisions more likely will reflect a balanced evaluation. Committee recommendations are not binding on FDA, but the Agency considers them carefully when deciding drug abuse issues.

FDA’s Anesthetic and Life Support Drugs Advisory Committee (the Committee), a panel of experts, has met twice within recent years to discuss the medical use of opioid analgesics, appropriate drug development plans to support approval of opioid analgesics, and strategies to communicate and manage the risks associated with opioid analgesics, particularly the risks of abuse of these drugs. The most recent meeting was held in September 2003. This meeting included DEA participation and the Committee included both pain specialists and addiction experts. At this meeting, Committee members again advised FDA that opioid medications are essential for relieving pain. Members emphasized that a balanced approach should be taken to both meet the needs of patients with pain as well as to minimize opiate analgesic misprescribing, abuse, addiction and diversion. They expressed a range of perspectives on the question of imposing restrictions on the prescribing of potent opioids. The pain specialists were concerned

about hurting legitimate patients and reversing the progress in the appropriate treatment of pain as efforts were increased to address abuse and misuse, while the drug addiction experts urged more constraints on use.

THE IMPORTANCE OF RISK MANAGEMENT

Safety or risk assessment combined with efforts to minimize known risks comprise what FDA calls *risk management*. Risk management is the overall and ongoing process of assessing a product's benefits and risks, taking action as necessary to decrease known risks, and then tracking safety and making adjustments as necessary to assure that risks are kept in line with benefits.

As part of risk management, FDA may ask companies to collect specific information to improve the speed and sensitivity of detecting suspected safety problems. When this enhanced data collection is requested by FDA, it is called a pharmacovigilance plan. These exist for many long-acting and potent opioid products and contribute to safe use of the product by detecting, as rapidly as possible, adverse outcomes, including misuse, overdose, abuse and diversion. Once problems are detected there need to be actions to address them.

Actions to minimize risks that go beyond providing an informative package insert are called risk minimization action plans or RiskMAPs. These are strategic safety programs designed to decrease known product risks by using one or more interventions, such as specialized education or restrictions on typical prescribing, dispensing, or use. The small number of RiskMAPs that exist are largely customized programs, although consistent approaches are being sought, for example, in the control of drugs that cause birth defects, such as thalidomide and isotretinoin.

In light of Government Accountability Office (GAO) concerns expressed over OxyContin, FDA recently stated in its guidance to industry on risk minimization efforts, that opiate drug products have important benefits in alleviating pain, but are associated with significant risk of overdose, abuse, and addiction. FDA, therefore, recommended that sponsors of Schedule II controlled

substances, especially the Schedule II extended release or high concentration opiate drug products, consider developing RiskMAPs for these products.

It is FDA's expectation that pharmaceutical manufacturers with new drug applications for potent opiates will submit plans for a RiskMAP that contain a strategy for educating providers and patients on opiate use, as well as means of preventing, detecting, and addressing abuse and diversion. This RiskMAP should be implemented at the time the drug is marketed, particularly for extended-release or high concentration Schedule II opiate drug products. RiskMAPs for individual products would probably vary, depending upon the approved indications and product-specific considerations, including the product's safety profile, but, each RiskMAP would need to address elements such as the appropriate target patient populations and safe use of the product, as well as monitoring for adverse outcomes, including misuse, overdose, abuse and diversion. The Agency's general expectation for addressing issues of safety, including post-marketing surveillance and risk minimization strategies, are detailed in a set of guidances published by FDA in March 2005 as a response to the third authorization of the Prescription Drug Users Fee Act. These guidances can be found on the Agency's web page at the following address: http://www.fda.gov/cder/guidance/index.htm.

In response to reports of abuse and misuse of OxyContin, FDA worked with the manufacturer, Purdue Pharma, to develop a RiskMAP for this product. The program included strengthening OxyContin's warning label, educating healthcare professionals and the sponsor's sales staff, and developing a tracking system to identify and monitor abuse. In July 2001, Purdue Pharma, working in cooperation with FDA, significantly strengthened the warning and precaution sections in the labeling for OxyContin. The labeling now includes a "black box" warning, the strongest warning for an FDA approved product, which warns patients and physicians of the potentially lethal consequences of crushing the controlled-release tablets and injecting or snorting the contents. The indication for use was clarified to reflect that it is approved for the treatment of moderate to severe pain in patients who require around the clock narcotics for an extended period of time.

FDA MONITORS DRUG ADVERTISING AND PROMOTION

FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC), in CDER, is responsible for regulating prescription drug advertising and promotion. DDMAC's mission is to protect the public health by ensuring that prescription drug information is truthful, balanced, and communicated accurately. This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering optimal communication of labeling and promotional information to health care professionals and consumers.

FDA continues to monitor promotional materials for controlled substances, particularly for sustained release products, to ensure that claims are not false or misleading. Also, all product promotional materials must include information from "black box" warnings in the approved labeling. For example, the current approved product labeling for OxyContin contains a "black box" to convey serious risks associated with the use of the product. FDA has taken action against sponsors who violate this requirement or otherwise promote their product in a manner that is false or misleading. The sponsor of OxyContin was cited in May 2000 and January 2003 for advertisements that promoted OxyContin in a manner that is false or misleading. In response, the company agreed to correct the advertisements. In addition, in response to a January 2003 Warning Letter, the company published remedial corrective advertisements in the same medical journals that had run the initial misleading advertisements. We will continue to monitor promotional materials for these products and use our regulatory authority to its fullest extent to ensure that healthcare providers and patients are not subjected to false or misleading claims for these products. As well, FDA's Office of Criminal Investigations remains vigilant to the possibility of criminally fraudulent marketing that may contribute to the problem of dependence.

LETTERS TO HEALTH CARE PROFESSIONALS

When significant changes are made to a drug's labeling, FDA encourages the drug's sponsor to notify health care professionals. For example, after we received reports of OxyContin abuse and diversion resulting in serious consequences, including death, labeling changes were implemented. The sponsor distributed a "Dear Healthcare Professional" letter (issued July 18, 2001) to physicians, pharmacists, and other health professionals. The letter explained recent

changes to the labeling, including additional prescribing information, and highlighted the problems associated with the abuse and diversion of OxyContin.

PATIENT INFORMATION AND EDUCATION

An important component of FDA's strategic plan is to enable consumers to make smarter decisions by providing them with better information to weigh the benefits and risks of FDA-regulated products. FDA's website (*www.fda.gov*) includes information for patients on drug safety and side effects, public health alerts, and general information about major drugs. These web pages provide important information to patients regarding how to use their drug products safely. In an effort to educate health care providers and consumers about the risks associated with OxyContin, FDA created an OxyContin Drug Information web page (*www.fda.gov/cder/drug/ infopage/oxycontin /default.htm*). This page contains valuable information for consumers including the current approved labeling, approval letter, frequently asked questions, and articles on prescription drug abuse.

PALLADONE SUSPENSION

As noted previously, FDA monitors the safety of products after they are approved. On September 24, 2004, FDA approved Palladone (hydromorphone hydrochloride extended-release) Capsules for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock opioid analgesia with a high potency opioid for an extended period of time, generally weeks to months or longer. The active ingredient in Palladone, hydromorphone, is a Schedule II controlled substance.

When FDA approved Palladone, the Agency had evidence from laboratory abuse liability studies that alcohol could be used to extract hydromorphone from Palladone capsules. Neither the Agency nor the drug's sponsor anticipated that this laboratory finding predicted a potential for a life-threatening interaction with alcohol in patients.

Soon after Palladone was approved, FDA received new evidence that "dose-dumping" occurs in

patients if Palladone is taken along with alcohol. The drug's sponsor completed a study in 24 healthy men showing that, compared to taking Palladone alone, concentrations of hydromorphone in the blood were 5.5 times higher on average when the 12 mg Palladone extended release capsules (the lowest dose available) were taken with 8 ounces of 40% alcohol (80 proof, equivalent to typical liquors, such as whiskey).

Lower concentrations of alcohol showed smaller, but still potentially serious effects on the release of hydromorphone from Palladone. Studies showed that taking Palladone with 20% alcohol (equivalent to a mixed drink) or 4% alcohol (equivalent to a typical American beer) increased hydromorphone concentrations 1.9 and 1.03 times higher on average, respectively, compared to taking Palladone alone but some individuals had much higher exposures.

Based on this information, FDA determined that the current formulation of Palladone presented an unacceptable level of risk, even though FDA is not aware of any patients who have had life-threatening side effects from drinking alcohol while taking Palladone. On July 13, 2005, FDA issued a public health advisory to inform patients and health care providers that the sponsor of Palladone agreed to suspend sales and marketing of the drug because of the potential for severe side effects if the drug is taken with alcohol.

CONCLUSION

FDA recognizes the serious problem of prescription drug abuse. The Agency will continue to take steps to curb abuse and misuse of prescription drugs. Since this is a problem that is broad in its reach and implications, we are committed to collaborating with our partners – Federal, state and local officials, professional societies, and industry - to prevent abuse and help ensure that these important drugs remain available to appropriate patients.

I would like to thank the Subcommittee again for this opportunity to testify today on this important issue. I would be pleased to respond to any questions.